REMARKS

Licensing and Review has issued a second paper (mailed August 29, 2002) for the above-identified application, continuing to take the position that the disclosed invention may be "useful in the production or utilization of special nuclear material or atomic energy", citing 42 U.S.C. 2182. Applicants reiterate their earlier position by respectfully disagreeing in view of the following additional comments.

First, Applicants again point the Supervisory Legal Instruments Examiner (SLIE) to Applicant's paper filed July 15, 2002, which Applicants feel is fully responsive to the Form PTOL-456 issued in the above-identified application. Applicants continue to take the position that this Request for Reconsideration fully explains why the present invention should hold no interest to the Department of Energy (DOE). The PTO now takes the position that disclosure of "^{35}P" at page 37 of the specification (Applicants presume the paper was meant to recite "^{35}S") reveals of use of a radioactive isotope, which presumable triggers this review. It is important to note that recitation of ^{35}S within the specification is prophetic in nature; no more than an offer of standard techniques which are used day in and day out in biological research laboratories throughout the United States. Such techniques may be useful within the confines of such a research laboratory to learn more about the function of the claimed invention. There is no recitation in the pending claims as to a product or methodology which utilizes or incorporates a radioisotope or any other radioactive substance or component.

Applicants further take the position that if a mere disclosure of a radioactive isotope in Applicants specification triggers a review by the DOE, then such reviews should be commonplace for any applicant pursuing patent protection for any related subject matter which recites use of radioactive materials. This begs the question as to whether US Patents which disclose similar types of subject matter generated within similar laboratory environments have been afforded the same scrutiny as dictated in Form PTOL-456. Such US Patents will disclose and claim (1) similar subject matter to the above-identified application (i.e., DNA molecules encoding a mammalian proteins, such as but not limited to a related nuclear receptor protein; see results of Micropatent® search attached as Exhibit A) and (2) the use of radioactive isotopes to practice various related assays within the confines of the

laboratory. A survey of U.S. Patents in question are listed below, citing some but not all recitations of radiolabeled substances:

U.S. Patent No.	Exhibit #	Specification Locator
6,391,847	B	Column 10, line 26 Column 12, line 21
6,277,976	C	Column 02, line 65
6,248,520	D	See Column 14 Col. 30, line 65 - Col. 31, line 5 Column 52, lines 36-38
5,958,710	E	See Column 6 Column 10, lines 57-67
5,639,616	F	See Column 25 Column 34, lines 31-34 Column 35, lines 43-46 Column 38, lines 16-29

There is a definite correlation between disclosures which (1) recite isolated genes and corresponding expression of the protein of interest and (2) the use of low level amounts of radioisotopes to study various biological processes the gene or protein may be involved. It is evident that a more comprehensive review than the above review would find that the overwhelming majority of issued U.S. patents reciting isolated DNA and/or protein products will refer to the use of such radioisotopes in standard, everyday laboratory practices. Applicants respectfully take the position that use of such radioisotopes does not rise to level of scrutiny intended by 42 U.S.C. 2182. If that was the case, then, as noted above, virtually all of the thousands upon thousands of U.S. Patents which have issued to such inventions over the past 20 years would have already been funneled through the DOE for review. To the best of his knowledge the undersigned attorney, with practically 10 years experience of preparing and prosecuting such applications, does not recall another instance where a Form PTOL-456 form was issued in a case under his control.

Therefore, as noted in our previous correspondence filed July 15, 2002 Applicants further take the position that the above-identified application does not relate to any "special nuclear material or atomic energy." To this end, not such review by the DOE, under 42 U.S.C. 2182, is required or is in fact proper.

The undersigned attorney respectfully requests that a representative of the Licensing and Review group contact the undersigned attorney telephonically is any additional information or discussion is required in order to return this case to its normal prosecution slot.

Respectfully submitted,

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Date: October 11, 2002

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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
Washington, D.C. 20231

DOCKETED
SEP 4 - 2002
KATHLEEN KOLTKOWSKI

PATENT & TRADEMARK OFFICE
MAILED
AUG 28 2002

LICENSING & REVIEW

Merck and Co. Inc.
P. O. Box 2000
Rahway, NJ 07065-0907

In re Application of:
Fang Chen:
For Serial No. 10/090,090

DECISION ON
REQUEST FOR
RECONSIDERATION

Response Due By 10-12-02

Filed: March 4, 2002
For: **DNA MOLECULES ENCODING HUMAN NUCLEAR RECEPTOR PROTEIN nNR7-1 (as amended)**

This is a decision on the REQUEST FOR RECONSIDERATION filed July 15, 2002, responding to the communication (FORM PTOL-456) mailed June 12, 2002.

The request has been **DENIED** to the extent indicated below.

42 U.S.C. 2182 states in part **"... useful in the production or utilization of special nuclear material or atomic energy".** A review of the application file history reveals among other things the use of a radioactive isotope "^{35}P " as disclosed in at least page 37 of the instant specification. Therefore under the directions from the Department of Energy (DOE) this application has been made available to them under 42 U.S.C. 2182 since the following subject matter relates to at least one of the following:

G. Materials, apparatus and methods concerning isotope and/or radioactive source technology including those utilizing (including responsive to) radioactive sources in:

a. Life Sciences such as medicine (diagnostic and therapeutic), ecology, disease and pest control, animal husbandry, etc.

b. Industrial processes such as food processing, sterilization, polymer production, etc.

c. Investigations of the environment or the earth

H. Instruments employing a radioactive source and/or radioactivity detector in the operation thereof.

Applicant is reminded that a response is due within forty-five days of the mailing date of the communication (FORM PTOL-456). The communication having been mailed June 12, 2002.

Joanne P. Hodge
Supervisory Legal Instruments Examiner
Licensing and Review
Patent Technology Center 3600

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK & CO., INC.

By J. Mark Hand Date 10/11/02
Reg. No. 36,545

MicroPatent® PatSearch FullText: Patent List

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Search scope: US Granted ; Claims, Title or Abstract
Years: 1990-2002
Text: (nucleic adj2 acid or nucleotide adj2 sequence or DNA adj2 molecule) and SEQ adj2 ID and nuclear adj5 receptor

15 patents. (Unsorted)

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Search History

EXHIBIT A APPL. SER. NO. 10/090,080

☑ **Highlight the search terms in the full-text record**

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Check All **Uncheck All**

1. US6416957 B1 ☐ G01N 20020709 The Salk Institute for Biological Studies Ligand Pharmaceuticals, Inc. The Government of the United States of America
Method for modulating process mediated by farnesoid activated receptors

2. US6391847 B1 ☑ A01N 20020521 The Salk Institute for Biological Studies
Method, polypeptides, nucleotide sequence of XOR-6, a vitamin D-like receptor from xenopus

3. US6365372 B1 ☐ C12P 20020402 Saint Louis University
SNF2 related CBP activator protein (SRCAP)

4. US6300488 B1 ☐ C07N 20011009 The Salk Institute for Biological Studies
Modified lepidopteran receptors and hybrid multifunctional proteins for use i n transcription and regulation of transgene expression

5. US6277976 B1 ☑ C12N 20010821 Karo Bio AB
Or-1, an orphan receptor belonging to the nuclear receptor family

6. US6268173 B1 ☐ C12N 20010731 Institut Natural de la Sante et la Recherche Medicale Centre Natural de la Recherche Scientifique Universite Louis Pasteur Bristol-Myers Squibb Company
Polynucleotide encoding transcriptional intermediary factor-2

7. US6248520 B1 ☑ C12Q 20010619 The Rockefeller University
Nucleic acid molecules encoding nuclear hormone receptor coactivators and uses thereof

8. US6184353 B1 ☐ C07K 20010206 The Salk Institute for Biological Studies
Method for modulating processes mediated by farnesoid activated receptors

9. US6054295 A1 ☐ C12N 20000425 Merck & Co., Inc.
DNA molecules encoding human nuclear receptor proteins

10. US6005086 A1 ☐ C07H 19991221 The Salk Institute for Biological Studies
Farnesoid activated receptor polypeptides, and nucleic acid encoding the same

11. US5958710 A1 ☑ G01N 19990928 Karo Bio AB

Orphan receptor

12. US5770176 A1 ☐ A61K 19980623 Chiron Diagnostics Corporation

Assays for functional nuclear receptors

13. US5747661 A1 ☐ C12N 19980505 Howard Hughes Medical Institute

Retinoid-inducible response elements

14. US5639616 A1 ☑ C12N 19970617 Arch Development Corporation

Isolated nucleic acid encoding a ubiquitous nuclear receptor

15. US5403925 A1 ☐ C07H 19950404 The United States of America as represented by the Department of Health and Human Services

Nucleic acids encoding mammalian H-2RIIBP or RXR.sub..beta. and uses thereof

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